K003190 1 of 2

JUN 11 2001

510(k) SUMMARY

NeoThermia Corporation's En Bloc Biopsy System™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: September 9, 2000

Name of Device and Name/Address of Sponsor

Common or Usual Name: Electrosurgical Generator

Trade or Proprietary Name: En Bloc Biopsy System™

Classification Name: Electrosurgical Cutting & Coagulation Device & Accessories (21 C.F.R. § 878.4400)
Biopsy Instrument (21 C.F.R. § 876.1075)

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Predicate Devices

- U.S. Surgical's Minimally Invasive Breast Biopsy Instrumentation
- Biopsy Medical, Inc.'s Mammotome
- Applied Laparoscopy's Acucise ES Trocar
- Everest Medical Corporation's Monopolar Coagulating Polypectomy Snare

Intended Use

The en Bloc Biopsy System™ is intended for diagnostic sampling of breast tissue during a breast biopsy procedure.

Technological Characteristics

The En Bloc is a high frequency, vacuum-assisted electrosurgical device used to remove tissue by electrosurgical cutting and simultaneous capture of an incised tissue volume. The NeoThermia En Bloc™ consists of a hand-held biopsy handle, upon which the single-use En Bloc Biopsy Probe is attached, with an integral cable to connect the handle to the control unit. The Probe™ contains two sets of active electrodes at its distal end – a precursor electrode and cutting/capture electrodes. The shaft of the Probe™ is encased in a stainless steel cannula. An outer plastic sleeve surrounds this stainless steel cannula and an annular gap between the sleeve and the cannula provides a conduit for vacuum-assisted removal of the gaseous products of electrosurgical cutting and any liquids (*e.g.*, blood) that may accumulate at the distal end of the Probe during the biopsy procedure.

Performance Data

Testing of the device was conducted on bovine tissue to determine the characteristics of cut and captured tissue. The device was also used in porcine models to evaluate the ability of the NeoThermia En Bloc Biopsy System™ to cut and capture a predictable volume of tissue and to assess its suitability for post-biopsy pathology evaluation. It was determined that the NeoThermia En Bloc Biopsy System™ is capable of obtaining intact, unfragmented biopsy specimens having a predictable diameter and length and suitable for post-biopsy histopathologic examination.

Substantial Equivalence

En Bloc™ has the same general intended use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices. The NeoThermia En Bloc and its predicate device are all electrosurgical devices used to biopsy soft tissue. Although there are minor difference in the technological characteristics of the En Bloc™ and its predicate devices (*e.g.*, sample size diameter and the En Bloc's radiographic visualization) the bench and animal data show that those differences do not raise new questions of safety or efficacy. The En Bloc™ is substantially equivalent to U.S. Surgical's MIBB, Biopsy Medical, Inc.'s Mammotome; Applied Laparoscopy's Acucise ES Trocar, and Everest Medical Corporation's Monopolar Coagulating Polypectomy Snare.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1 2001

Ms. Sherrie Coval-Goldsmith
Vice President Regulatory Affairs
Neothermia
One Apple Hill
Suite 316
Natick, Massachusetts 01760

Re: K003190
Trade/Device Name: en-bloc biopsy system™
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI, KNW
Dated: May 25, 2001
Received: May 25, 2001

Dear Ms. Coval-Goldsmith:

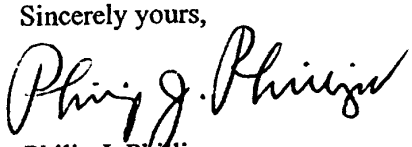
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Philip J. Phillips
Deputy Director for Science and
Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K003190

Device Name: **Neothermia Corporation en- bloc Biopsy System™**

Indications for Use:

The en Bloc Biopsy System™ is intended for diagnostic sampling of breast tissue during a breast biopsy procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR over-the-counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003190